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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,223	08/12/1999	GEORG KALLMEYER	P8341-9011	5876

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	09/308,223	KALLMEYER ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/23/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *13 and 15-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of the application has changed. This case has now been transferred as of March 3, 2005. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Brandon Fetterolf, Group Art Unit 1642.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/04/2003 has been entered.

The Amendment to the claims faxed to Examiner Nickol on 02/23/2005 in response to the telephone conversation (02/18/2005) is acknowledged and has been entered.

Claims 13 and 15-36 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action of 6/04/2002.

Rejections Maintained:

Claims 13, 15-21, and 23-36 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by Andya *et al.* (US Patent No. 6,267,958, March 1996) for the reasons of record in the prior Office Action (10/16/2000, pages 3-4).

Applicant's assert (Page 4) that "claims 13 and 27 are directed to a lyophilizate and claim 36 is directed to a method of preparing the lyophilizate wherein the lyophilizate contains **no** (*emphasis added*) polyethylene glycols or additional proteins." Applicant's further contend that both the supporting disclosure and the examples in the present specification indicate that the described

formulations appear to specifically exclude the use of polyethylene glycol and additional proteins. Specifically, Applicant's point to the supporting disclosure on page 6, last paragraph of the specification which indicates the preferred exclusion of these components. Thus, Applicant's ague that although the present claimed inventive composition and process fall within the general field of art for lyophilizates as Andya's composition and process, one skilled in the art would not have even considered the instant claimed composition and process as being disclosed by or inherent to the composition or process of Andya. These arguments have been considered but are not found persuasive.

Applicants argument that one skilled in the art **would not have even considered** (*emphasis added*) the instant claimed composition and process as being disclosed by or inherent to the composition of Andya is moot because Applicants have not provided evidence to the contrary. For example, if one skilled in the art was to carefully consider the present application (i.e., pending claims, examples, disclosure) in light of the prior arts disclosure, one skilled in the art would come to a conclusion that the instant claimed composition and process is disclosed by or inherent to the composition and process of Andya for the following reasons: First, while Applicants allege that claims 13 and 27 are directed to a lyophilizate and claim 36 is directed to a method of preparing the lyophilizate wherein the lyophilizate contains no polyethylene glycol or additional proteins, Applicants have not provided evidence to the contrary or established a patentable difference between the method or product used in the prior art and the current pending claims. For example, the claimed lyophilizate and claimed method of preparing the lyophilizate of Andya does not appear to specifically require polyethylene glycol or additional proteins (see columns 31, line 53 to column 34, line 42). Thus, any argument alleging that the present claims differ from the prior art because of the limitation "no polyethylene glycol or additional proteins" is not pertinent because this says nothing about the patentable difference between the method or product used in the prior art and the current pending claims. Secondly, although the specification appears to provide examples describing formulations excluding the use of polyethylene glycol and additional proteins, Applicants assertion that the specification on page 6, last paragraph indicates the exclusion of the these compounds is misleading because the specification (page 6, last paragraph) teaches that "the object of the invention was to provide a stable pharmaceutical preparation of monoclonal or polyclonal antibodies that is **essentially free** (*emphasis added*) of the above mentioned polymers (*i.e., polyethylene glycol*) or

proteinaceous pharmaceutical auxiliary substances". Thus, the supporting disclosure as a whole does not exclude polyethylene glycol or additional proteins. In addition, a careful review of the prior arts disclosure appears to provide examples (column 18 line 55 to column 34, line 42) describing formulations **excluding** (*emphasis added*) the use of polyethylene glycol and additional proteins. Therefore, one skilled in the art would have considered the instant claimed composition and process as being disclosed by or inherent to the composition or process of Andya.

Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Claims 13, and 15-36 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Andya *et al.* (US Patent No. 6,267,958, March 1996) in view of Michaelis *et al.* (US Patent No. 5,919,443, June 1995) for the reasons of record in the prior Office Action (10/16/2000, pages 5-6).

Applicant's argue (page 5) that the prima facie obviousness case fails for the reason that the combination of elements for the invention of Claims 13 and 15-36 are not disclosed by Andya or Michaelis alone or in combination. Applicants further assert, as described above, that the pending lyophilizate claimed contains no polyethylene glycol or additional proteins and that both the supporting disclosure and the examplesin the present specification, as described above, indicate that the described formulations appear to specifically exclude the use of polyethylene glycol and additional proteins.

This argument has been considered but is not found persuasive.

First, the suggestion to combine was based on the advantages of an improved lyophilizate since Michaelis *et al.* make the surprising discovery that is possible to produce stable forms of pharmaceutical agents when amino sugars are used as additives (see page 6). Also, it appears that applicant has argued and discussed the references individually without clearly addressing the combined teachings, particularly in view of the fact that both references represent analogous teachings comprising the preparation of stable pharmaceutical compositions. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d

413,208 USPQ 871 (CCPA 1981). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Therefore, NO claim is allowed

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER